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Bone Anchored and Middle Ear Implant Hearing Aids

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Implantable hearing aids comprise two distinct subgroups: bone anchored hearing aids (BAHA) and middle ear implants (MEI). Both require surgeries and both require that some portion, or an entire device, be implanted either behind the ear in the mastoid area (BAHA) or in the middle ear cavity (MEI). Depending on the manufacturer, some MEIs also require that some components be implanted in the mastoid area. Other than these two common points, these implantable aids differ in use and function. The BAHA is used for those with conductive or mixed hearing loss, while the MEI is used most often for those with sensorineural hearing loss. Historically, some MEIs were designed for use with conductive hearing losses, but the vast majority of MEIs are to be used in patients with sensorineural hearing losses.

Overview of the Bone Anchored Hearing Aid

A BAHA is the general name for any hearing device that is anchored to the mastoid bone. BAHA is also the model name of the device manufactured by Entific, and is the only bone anchored hearing aid that is available in the marketplace. When referring to the device marketed by Entific, BAHA® will be used. The Entific BAHA® is designed for those patients (5 years of age or older) who have either a conductive hearing loss, or a mixed hearing loss where the bone conduction thresholds (averaged at 500 Hz, 1000 Hz, 2000 Hz, and 3000 Hz) do not exceed 45 dB for the ear-worn device (approved by the FDA) and up to 65 dB for the body-worn device (approved in many European countries, Asia, Canada, and Australia). That is, a patient may have a significant conductive loss and a significant sensorineural component and still be a candidate. As an extreme example, a patient may have a moderate sensorineural component with no measurable air conduction thresholds and still be a successful candidate for a BAHA. An advantage of a BAHA over conventional air conduction hearing aids is that nothing is placed in the ear canal, thereby minimizing the incidence of repeated ear infection in the case of chronic unresolvable otitis media, and allowing efficient conduction of sound in the case of those with congenital atresias or malformed outer and/or middle ears.

Ideal patients for BAHAs are those with congenital atresias (such as those with Treacher Collins and Goldenhar's syndromes) or those with chronic unresolvable middle ear dysfunction who have had limited success with conventional air conduction hearing aids. A small group of patients with unresolvable external otitis, or those who cannot wear earmolds have also derived

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benefit. The Entific BAHA® has been in clinical use since 1977, and to date, over 9000 people have been fit worldwide. Figure 1 shows both the ear level external sound processor and the implanted abutment.

Historically, there are two approaches to the BAHA: transcutaneous (over the skin) and percutaneous (through the skin). The transcutaneous approach uses the same approach as found in most modern cochlear implants—a small magnet is implanted under the skin in the mastoid area, and the external sound is transduced from an external coil held in place electromagnetically, through the skin to the implanted magnet. The magnet is held rigidly by the bone in the mastoid area, and mechanovibratory energy is transmitted to the cochlea.

This method has a small layer of intact skin between the external coil and the implanted magnet. Unfortunately, this layer of skin provides significant attenuation of the signal and creates an uncontrollable frequency response. The gain and output can vary from patient to patient, depending on the success of the surgery and the amount of tissue left over the implant site. An example of a transcutaneous bone anchored hearing aid was the Xomed Audiant™. Because of these inherent problems, the Audiant™ was withdrawn from the marketplace in the mid-1990s.

In contrast, the percutaneous method requires no layer of skin. The implanted magnet is connected to a small abutment that protrudes through the skin. The external aid can then be coupled directly to the permanent abutment. Such "hard wiring" results in a stronger and predictable signal being transduced to the cochlea. With this approach, there is a very slight chance that infection may occur around the implant site. The only example of the percutaneous approach is the BAHA® from Entific, and it is this device that has been successfully used around the world. The percutaneous nature of the BAHA® means that it not only will provide a significantly better fitting for selected patients, but will also provide significantly more gain and high-frequency output than conventional bone conduction hearing aids. Indeed, the use of a BAHA® will improve the articulation index (proportion of audible speech cues) by 18% to 20% over a well fit conventional bone conduction hearing aid (Chasin, 2000a). Because the BAHA® yields a better fidelity sound than conventional bone conduction hearing aids, it has been successfully recommended for children as well as adults. Any future development of the bone anchored hearing aid must be percutaneous because of the inherent problems with the transcutaneous approach.

Overview of Middle Ear Implants

In contrast to the bone anchored hearing aid, MEIs have only recently been approved by the

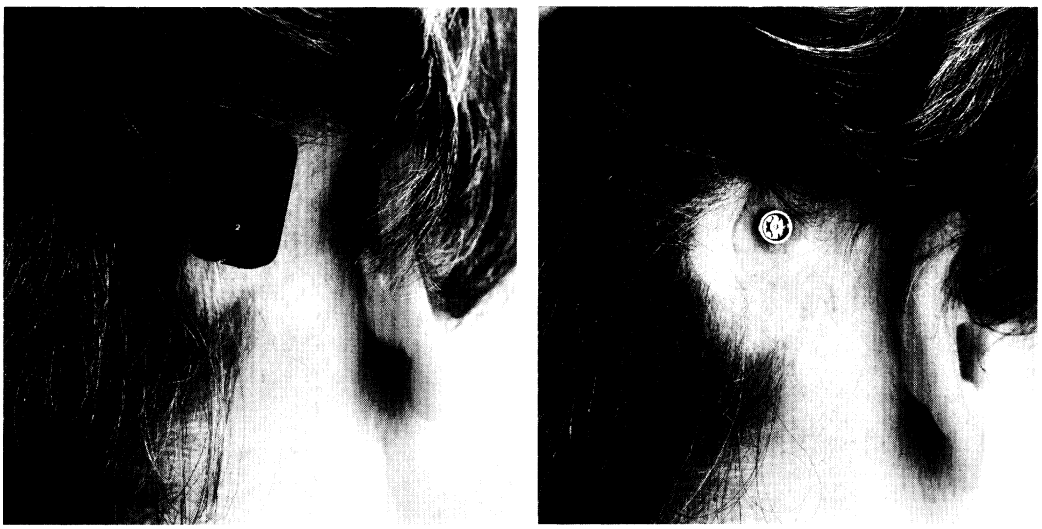

Figure 1. The ear level (Compact) BAHA™ and the percutaneous abutment.

various regulatory agencies around the world. MEIs have been in existence, at least in a research environment, since Dr. Wilska (1935, in Goode, 1989) sprinkled iron filings onto the eardrum of a patient while the patient was lying prone on a medical couch. He applied a strong magnetic field encased in an earphone over the test ear, and the patient reported hearing sound, despite the absence of an acoustic signal. The flux of the magnetic field caused the iron filings to vibrate in synchrony, which in turn caused vibration of the eardrum. From that point on, the transduction of sound was identical to conventional acoustic stimulation. Spindel *et al.,* (1995) noted that sound transduced by conventional air conduction and sound transduced through an electromagnetic route to the cochlea were essentially the same ($r = 0.94$).

The problems with the Wilska device were obvious—the patient had to remain motionless while lying down, and a very high amount of current was necessary to generate a significant enough magnetic field. Because of these issues, very little progress was made in magnetic stimulation of the ear until the 1970s and 1980s. As a result of improved technology, the high current problem has all but been resolved. In the 1950s approximately 28,000 milliamps was required to generate 80 dB SPL, but only about 3 milliamps is required with current MEIs.

The first clinically wearable device was introduced in Japan by Drs. Suzuki and Yanagihara. (see Chasin, 1997, for review). This device was designed for patients with chronic middle ear dysfunction, and although corporate funding has been withdrawn from this program, limited research is still being performed on this device. All other MEIs that are being marketed, other than this Japanese device, are for those patients with completely normal middle ear function who have a totally sensorineural hearing loss. Therefore, the ideal candidate is one who has a completely sensorineural hearing loss, and who has tried conventional hearing aids in the past with limited success. This limited success may be related to chronic acoustic feedback, or lack of sufficient high-frequency amplification, which are, of course, related.

Wilska's device, which uses an electrically based magnetic field "transmitter" and a magnet "receiver," is only one way of producing a viable middle ear implant. Another is an electromagnetic MEI, which uses an external coil connected to a microphone, an amplifier, and an implanted magnet (usually, but not always situated on the ossicles). Some manufacturers have designed an electromechanical version where an implanted magnet "drives" a piston, or other transducer, that is directly connected with the ossicular chain. These implants are an improvement on Dr. Wilska's device because the magnet or electromechanical receiver is implanted in the middle ear cavity, and not just on the eardrum. They are significantly more efficient.

Although Fredrickson *et al.,* (1973) first reported on the modern version of the electromagnetic MEI over 25 years ago, a device developed from work by his group has only recently achieved commercial status in Europe with the CE mark of approval. (Otologics Middle Ear Transducer™ [MET™]). It is also undergoing clinical trials under the auspices of the FDA for future commercial distribution in the US market. Two other commercially available electromagnetic MEI devices are the Soundtec Direct Drive Hearing System (Soundtec DDHS™) and the Symphonix Vibrant® Soundbridge. The Symphonix device has received regulatory approval for sale and the US and the CE mark for distribution in Europe. The Soundtec Direct Drive System is approved for commercial use in both the US and Canadian markets.

The Otologics MET™ and the Symphonix Vibrant® Soundbridge are both examples of an electromechanical form of transduction—a transducer "vibrates" the ossicular chain that has been set in movement by an electromagnetic field. The Soundtec DDHS™ is an example of an electromagnetic MEI where the magnet is connected directly to the ossicular chain. Locations of the various transducers of these three electromagnetic and electromechanical MEIs are shown in Figure 2.

All electromagnetic or electromechanical MEIs have three essential features that characterize usage and form: (1) this type of transduction is very efficient (with an impedance on the order of 10^2–10^3) meaning that, at least in theory, levels in excess of 130 dB SPL can be achieved. In reality, the actual outputs are far less than 130 dB SPL, and tend to be on the order of 110 to 115 dB SPL. The potential is there for more gain and output in future generations of the devices as the technology improves; (2) currently, no electromagnetic or electromechanical MEI is small enough to be completely implanted in the middle ear. Consequently, all electromagnetic or electro-

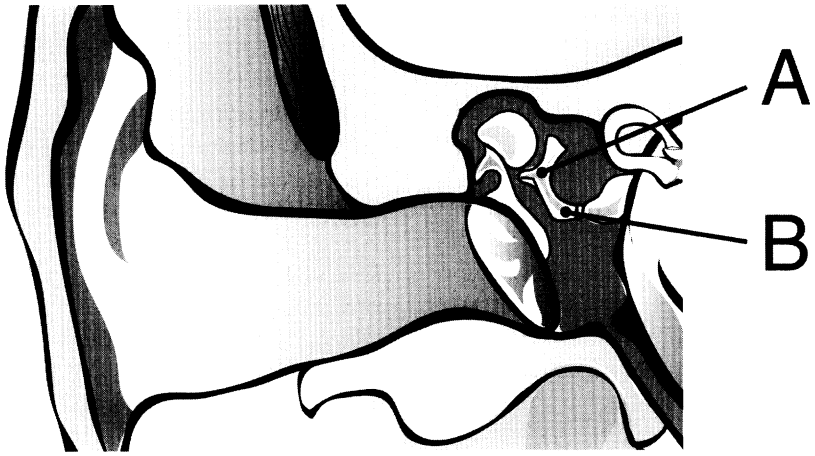

Figure 2. The position of the transducers of three MEIs: **(A)** Otologics electromechanical device, and **(B)** Symphonix electromechanical device and also location of the Soundtec electromagnet.

mechanical MEIs currently approved or under review are partially implanted; (3) where the magnet is placed on the ossicular chain is a factor that is quite important for the electromagnetic MEI such as the Soundtec DDHS™ (rather than the electromechanical MEIs). The more medial (nearer the cochlea) the magnet is placed, the more high-frequency sound transmission there may be, due to the rotational characteristics of the ossicular chain at higher frequencies.

One technical concern of the electromagnetic approach is that the magnet may cause a slight high-frequency conductive hearing loss due to an increase of mass (usually this is not a major problem however if the implanted magnet is less than 50 mg.). Another concern relates to undesirable resonances that the magnet/ossicular chain combination may generate. The more lateral (towards the eardrum) the magnet is placed, the closer it is to the external magnetic coil and the stronger the transduced sound. This is not as important for the electromechanical form of transduction. A balance of transduced strength and high-frequency transmission defines the optimal magnet location.

In most electromagnetic MEI systems, the magnet is located at or near the incudostapedial joint. There are some ingenious forms of coupling the magnetic vibrations to the ossicular chain. For example, the Symphonix Vibrant® Soundbridge contains a sophisticated "floating mass transducer" that can be crimped on to the ossicular chain. In the case of the Otologics MET™, there is no magnet on the ossicular chain. A small probe is inserted into the incus and this vibrates the ossicular chain as a result of electromagnetic stimulation. With the Soundtec DDHS™ device, a magnet is inserted on a holder that slips over the incudostapedial joint (after a temporary disarticulation).

All use safe and reliable surgical procedures, but both the Otologics and Symphonix devices require a general anaesthetic and mastoid entrance. The Soundtec device is placed down the ear canal under local anaesthetic. An advantage of the Soundtec device is the minor surgical procedure, but a disadvantage is that a hearing aid shell containing the electromagnetic coil needs to be placed in the ear canal. The Otologics and the Symphonix devices do not require anything in the ear canal.

In contrast to the electromagnetic (and electromechanical) MEI systems, another MEI approach (see Chasin, 1997 for review) was also developed in the 1970s using a small piezoelectric crystal connected to the ossicular chain, or in some implementations, replacing the more lateral portions of the chain. A piezoelectric crystal generates current when physically bent. It also bends when a current is applied. In this way, a piezoelectric crystal can function as both a microphone and a receiver—albeit with different efficiencies. The structure is remarkably simple: An external microphone transduces sound to the crystal that is implanted in the middle ear. This received current causes the crystal to bend, which

in turn, causes the ossicular chain to vibrate in synchrony. Two piezoelectric MEIs that either have been used in experimental research on humans or have received some form of regulatory approval are the St. Croix Medical Envoy™ and the Implex Totally Implantable Cochlear Amplifier (TICA™). The St. Croix Medical device has only been used in animal research in the US and in some experimental work on humans in Europe. The Implex device has been approved for European distribution and has the CE mark, although it has recently been withdrawn from the market because of financial concerns. The Implex patents have been sold to other stakeholders in the industry and the device may again surface in the future. These devices use versions of a system whereby the microphone is the eardrum or is implanted in the posterior portion of the outer ear canal wall.

Two essential features of the piezoelectric form of MEI characterize its usage. The first, is that the packaging of this form of MEI is quite small (and simple) so that the two available types are totally implantable. The St. Croix Medical Envoy™ uses the eardrum as the microphone and the Implex TICA™ device uses a small microphone situated under a flap of skin in the posterior portion of the ear canal wall. Since they are totally implantable, the battery is either rechargeable (Implex) or is reported to last 4 to 5 years (St. Croix Medical). The second feature is that this type of transduction is significantly less efficient than its electromagnetic and electromechanical counterparts. Its impedance is on the order of about 10^7 to 10^9, such that the maximum possible output is about 110 dB SPL. Its gain is therefore limited to about 30 to 40 dB, which would make it useful for moderate- to moderately-severe sensorineural hearing losses at most.

One obvious advantage of the piezoelectric MEI, in its current form, is that it is completely implantable. With a maximum gain of 30 to 40 dB, one needs to question whether a completely-in-the-canal hearing aid would be a viable alternative if the cosmetic issue is the only concern. Currently all MEIs are transcutaneous (similar in transduction to cochlear implants). Most people working in MEI research acknowledge that significantly more gain and output could be achieved with a percutaneous method of transduction, and perhaps this may be a trend in the future. With the potential output of the electromagnetic MEIs, this may pose an alternative to a cochlear implant with some patients.

How Are Bone Anchored Hearing Aids and MEIs Tested?

Clearly bone anchored hearing aids and MEIs cannot be tested with routine real ear measurement techniques. Other than various questionnaires, and various speech-in-noise tests, how can frequency specific information be obtained? Functional gain testing can be used, with some limitations. A complete discussion of these limitations, as well as alternative strategies for this type of hearing aid, can be found in Chasin (2001b). As a summary, functional gain testing can be useful as long as one is sure that the non-test ear is not responding, and if one's equipment can generate a sufficiently intense signal to ascertain the unaided portion of the functional gain measurement. More often than not however, especially with patients with a significant conductive hearing loss (eg bone anchored hearing aid candidates), the non-test ear cannot be sufficiently isolated.

A useful alternative for both bone anchored hearing aids and MEIs is to assess the "aided" portion of the functional gain measurement only and convert to the equivalent HL such that it can be written on the audiogram. Both of these hearing aids need to be assessed in a sound field, so not only does the minimal audible field to minimal audible pressure conversion need to be made, but the exact calibration of the sound field needs to be established.

The sound field calibration section of the American National Standards Institute S3.6 (1996) standard can be used to make this conversion. To verify the calibration and appropriate conversion, the exact sound pressure level can be checked by using either a real ear measurement system in its "stimulus off" mode or by using a sound level meter. This calibration check only needs to be performed once. Once calibrated/verified, the dial readings of the aided measurements can be written directly on the audiogram as a measure of functional benefit that is frequency specific. The details of this calibration and assessment procedure can be found in Chasin (2000b).

An advantage of functional gain testing (if a sufficient signal can be generated for the unaided portion, and one can "remove" the non-test ear from the calculation) is that non-linear hearing aids can be easily assessed in their linear mode. That is, the aided portion of functional gain can

Table 1. A Summary of Five Middle Ear Implant Systems

Manufacturer	Status	Type	Location of Microphone	Location of Transducer
Implex	CE mark*	Piezo	Ear canal wall	Head of stapes
Otologics LLC	FDA trial and CE mark	EMe	Button-BTE	Probe in incus
Soundtec	FDA approval and Cdn. approval	EM	In-the-ear shell	Incudo-stapedial
St. Croix Medical	Experiment. only	Piezo	Eardrum	Head of stapes
Symphonix	FDA approval and CE mark	EMe	Button-BTE	Incudo-stapedial

CE = European approval; CE mark* = no longer in business; Piezo = piezoelectric; EM = electromagnetic; EMe = Electromechanical.

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utilize a signal level that is low enough such that compression circuitry is not activated. There may be a problem, however, with those devices that use expansion circuitry and which may give an erroneous result at low-intensity stimulus levels.

Otologics has developed a system called the "Reference Transmitter/Receiver" that directly stimulates the MEI without amplification so that an electromechanical "audiogram" can be measured. The system also allows the external portion to be evaluated on a standard hearing aid analyzer. In addition, some of the MEIs are either digital or digitally-programmable, which opens the possibility of evaluating function indirectly by assessing the frequency-gain-output parameters on the programmer.

Table 1 summarizes the salient characteristics of each of the MEI systems that are discussed. The electromagnetic/electromechanical and piezoelectric MEIs are two implementations of a new type of hearing aid. Both types can use the latest hearing aid technology and most can be updated with minimal effort. Patients who have had limited success with their current amplification due to reasons of acoustic feedback or limited high-frequency amplification, may find MEIs to be a viable alternative. Feedback can still be a problem, but it will be less so, than for conventional hearing aids.

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